DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 12, 2014

Agfa HealthCare N.V.
% ShaeAnn Cavanagh, RAC
Regulatory Affairs Specialist NA
AGFA Healthcare
10 South Academy Street
GREENVILLE SC 29601

Re: K141602
Trade/Device Name: DX-D Imaging Package
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: June 13, 2014
Received: June 16, 2014

Dear Ms. Cavanagh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141602

Device Name

DX-D Imaging Package

Indications for Use *(Describe)*

Agfa HealthCare's DX-D Imaging Package is indicated for use in general projection radiographic applications to capture for display diagnostic quality radiographic images of human anatomy for adult, pediatric and neonatal examinations. The DX-D Imaging Package may be used wherever conventional screen-film systems, CR or DR systems may be used.

Agfa HealthCare's DX-D Imaging Package is not indicated for use in mammography.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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FORM FDA 3881 (1/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

510(K) SUMMARY

Agfa DX-D Imaging Package Dose Reduction

Common Name: Solid State X-Ray Imager (Flat Panel/Digital Imager)
Classification Name: Stationary X-Ray System
Regulatory Classification: 21 CFR 892.1680
Product Code: MQB
Proprietary Name: DX-D Imaging Package
Agfa HealthCare N.V.
Septestraat 27
B-2640 Mortsel
Belgium
Contact: Koen Vervoort, Prepared: June 13, 2014
Telephone: +32-34444-7368

A. LEGALLY MARKETED PREDICATE DEVICES

This is a 510(k) for Agfa HealthCare's DX-D Imaging Package, a solid state x-ray imaging device. It is substantially equivalent to a previous version of Agfa HealthCare's DX-D Imaging Package (K122736) and CR Systems with DX-G Digitizers (K092238).

B. DEVICE DESCRIPTION

Agfa HealthCare's DX-D Imaging Package is a solid state x-ray system, a direct radiography (DR) system (product code MQB) intended to capture images of the human body. It is a combination of Agfa HealthCare's NX Workstation, one or more flat-panel detectors, needle-phosphor detectors for direct radiography (DR) applications.

DX-D Imaging Package uses the NX Workstation to process data utilizing Agfa HealthCare's MUSICA image processing software, which includes optional image processing algorithms for adult, pediatric and neonatal images that were previously cleared for use in Agfa HealthCare's DX-D Imaging Package (K122736). The acronym MUSICA stands for **Mu**lti-**S**cale-**I**mage-**C**ontrast-**A**mplification. MUSICA acts on the acquired images to preferentially enhance the diagnostically relevant, moderate and subtle contrasts.

This submission is to obtain clearance for Agfa HealthCare to market the DX-D Imaging Package using a minimum of 50% dose reduction marketing claims.

Principles of operation and technological characteristics of the DX-D Imaging Package and predicate devices are the same. The DX-D Imaging Package is physically and electronically identical to the predicate K122736 since it is the same device; however, Agfa HealthCare would like to include a minimum of 50% dose reduction claims for marketing purposes. It uses the same workstation and same scintillator-photodetector flat panel detectors, needle-phosphor detectors and cassettes, or photo-stimulable imaging plates to capture and digitize the image.

Laboratory data and image quality evaluations conducted with board-certified radiologists confirm that performance is equivalent to the predicates.

C. INTENDED USE

Agfa HealthCare's DX-D Imaging Package is indicated for use in general projection radiographic applications to capture for display diagnostic quality radiographic images of human anatomy for adult, pediatric and neonatal examinations. The DX-D Imaging Package may be used wherever conventional screen-film systems, CR or DR systems may be used.

Agfa HealthCare's DX-D Imaging Package is not indicated for use in mammography.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

Agfa HealthCare's DX-D Imaging Package has an Indications For Use statement identical the predicate device (K122736) and similar to predicate device (K092238). Intended uses are the same. The devices have the same technological characteristics.

The DX-D Imaging Package indications for use is equivalent to both predicates (K122736 and K092238). Both the DX-D Imaging Packag and predicate devices (K122736 and K092238) include the statement that the device is not indicated for mammography, and include pediatric and neonatal patient populations. The predicate device (K092238) includes system options and accessories; which are also available on the DX-D Imaging Package and predicate K122736. Differences in devices do not alter the intended diagnostic effect.

The DX-D Imaging Package and the Agfa HealthCare predicate device (K122736) are solid state imaging devices, Product Code MQB. Agfa HealthCare's DX-D Imaging Package is substantially equivalent to both predicate devices (K122736 and K092238) in that it uses precisely the same technology to capture and transmit images.

There is no difference between the DX-D Imaging Package and predicate K122736. The DX-D Imaging Package includes cassettes and image plates which are included in predicate K092238. There are no changes to the intended use/indications of the device. The DX-D Imaging Package uses the same NX Workstation, the same detectors, and same cassettes and image plates as both predicates (K122736 and K092238).

Image evaluations and laboratory testing was completed that confirm a minimum of 50% dose reduction was achieved using the DX-D30C/DX-D35C flat panel detector or the CR HD5.0 imaging plate compared to the CR MD4.0 imaging plate.

Performance data including laboratory image quality measurements and image comparison studies by board-certified radiologists are adequate to ensure equivalence.

PRODUCT COMPARISON TABLE			
	DX-D Imaging Package (New Device)	**AGFA DX-D Imaging Package (PREDICATE-K122736)**	**AGFA CR Systems with DX-G Digitizers (PREDICATE-** K092238**)**
Communications	Same as predicates	DICOM	DICOM
Flat Panel or Image Plate	Same as K092238	Flat Panel Detector	Image Plates with Cassettes
Detector Material	Same as predicates	Gadolinium Oxysulfide (GOS) or Cesium Iodide (CSI) scintillator	HD5.0 (CsBr:Eu) MD4.0 (BaSrFBrI:Eu)
Detector Sizes	Same as predicates	17x17 in. 14x17 in.	14x17 in. 14x14in. 8x10 in. 10x12 in
Active Matrix (14x17 in.)	Same as K122736	2560x3072	3408 x 4200 (HD5.0) 2320 x 2832 (MD4.0)
Pixel size	Same as K122736	139 μm	100 μm
Dynamic Range	Same as K122736	14 bit	12 bit
Maximum Image Acquisitions/hr.	Same as K122736	150	100
Power Supply	Same as predicates	50-60 Hz 100-240V auto ranging	50-60 Hz 100-240V auto ranging
Operator Workstation	Same as predicates	Agfa NX	Agfa NX
Image processing	Same as predicates	MUSICA 3 MUSICA^2	MUSICA^2
Operating system	Window 7	Windows XP Pro	Windows XP Pro
Display System	Same as predicates	Standard PC display or separately cleared medical display (e.g. K051901)	Standard PC display or separately cleared medical display (e.g. K051901)

E. TECHNOLOGICAL CHARACTERISTICS

Agfa HealthCare's DX-D Imaging Package is a solid state x-ray system, a direct radiography (DR) system (product code MQB) intended to capture images of the human body. It is a combination of Agfa HealthCare's NX Workstation, one or more flat-panel detectors, needle-phosphor detectors for direct radiography (DR) applications. The NX Workstation allows users to view and processes images, and forward them to other devices (e.g. a PACS or printer).

Principles of operation and technological characteristics of the DX-D Imaging Package and predicate devices are the same. The DX-D Imaging Package is physically and electronically identical to the predicate K122736 since it is the same device; however, Agfa HealthCare would like to include a minimum of 50% dose reduction claims for marketing purposes. It uses the same workstation and same scintillator-photodetector flat panel detectors, needle-phosphor detectors and cassettes, or photo-stimulable imaging plates to capture and digitize the image.

The DX-D Imaging Package is integrated with compatible x-ray systems such as the DX-D 100 (K103597), DX-D 300 (K103050), DX-D 600 (K112670), DX-G (K092238), DX-M (K111324), and CR 30-X (K062223).

F. TESTING

Laboratory testing and image evaluations using equivalent test protocols as used for the cleared detectors and imaging plates were evaluated by qualified individuals employed by the sponsor to demonstrate that adequate design controls (according to 21 CFR 820.30) were in place.

- **DQE Image Quality Technical Evaluation**
  A laboratory image quality technical evaluation was performed comparing the computed radiography and direct radiography detectors. Values are provided for Detective Quantum Efficiency (DQE) for the direct radiography Cesium Iodide (CsI) flat panel detector (DX-D35C), the computed radiography Cesium Bromide (CsBr) HD5.0 imaging plate, and the computed radiography Barium Fluoro-bromide (BaFBr) MD4.0 imaging plate.

  The technical evaluation of the CsBr CR and the CsI DR illustrated a similar image quality for both systems at RQA3 and RQA5 beam qualities. Some differences can be indicated, which might be used in specific applications to optimize image quality. Both systems have better image quality than the predicate device (CR MD4.0); the DQE is more than double that of the predicate device (CR MD4.0).

  The DQE is generally accepted to be the most suitable parameter for describing the imaging performance of an X-ray imaging device. It describes the ability of the imaging device to preserve the signal-to-noise ratio from the radiation scene to the resulting digital image. Since in X-ray imaging, the noise in the radiation field is intimately coupled to the air kerma level, DQE values can be considered to describe the dose efficiency of the device. The higher DQE for the CsBr CR and CsI DR as compared to the predicate device, guarantees that with both systems, the same image quality can be obtained as for the predicate device but at significant lower exposure level.

  Agfa used generally accepted standards such as IEC 62220-1 when doing DQE testing. The range of exposure and doses used were designed to cover the normal ranges encountered in clinical use.

- **CR MD4.0 (BaFBr -PIP) vs. CR HD5.0 (CsBr-NIP) & DX-D30C (CsI-NIP) Comparison**

  An image quality evaluation was conducted with five board certified radiologists. The goal was to demonstrate that a minimum of 50% dose reduction can be achieved when using the DR DX-D30C flat panel detector or the CR HD5.0 image plate instead of the CR MD4.0 imaging plate. The study compared the computed radiography (CR) MD4.0 imaging plates to a DX-D30C digital radiography (DR) flat panel detector and to computed radiography (CR) HD5.0 imaging plates. The study confirmed that the dosage using the DR system DX-D30C and CR system HD5.0 was at least 50% lower than the CR system MD4.0.

  The evaluation used five different anatomical phantoms; skull, chest, hand, abdomen and neonatal. Each phantom type was exposed using each detector type. For each condition (phantom and detector type) all the exposure parameters (kVp, grid, distance, etc) remained

the same except the time (ms) which was varied. For each condition 13 exposures were made with a difference between exposures of 0.10 log E, the total range of exposures from highest to lowest was a factor of 16 times or 1.2 log E. All the acquired images were processed with the appropriate Musica[2] and Musica 3 settings. This resulted in 13 exposures for each condition with 39 exposures on each phantom for a total of 195 images.

	Detector name and (Phosphor Type)			
Phantom Type	**MD 4.0 (BaFBr)**	**HD 5.0 (CsBr)**	**DX-D 30c (CsI)**	**Total Exposures**
Skull	**13**	**13**	**13**	**39**
Chest	**13**	**13**	**13**	**39**
Abdomen	**13**	**13**	**13**	**39**
Hand	**13**	**13**	**13**	**39**
Neonatal	**13**	**13**	**13**	**39**
Total Exposures	**65**	**65**	**65**	**195**

The images were displayed on a high quality diagnostic monitor. The left image was always the reference image; the right image was the image under evaluation. The left (reference) image was always exposed with a specific detector (CR MD 4.0) at a fixed exposure condition; the right images were a series of 13 images from a different detector type (CR HD5.0 or DR DX-D30C) to be compared to the reference image. The right (test) images were varied from high to low exposure while the left image remained the same.

For each condition the radiologists were asked to match the test images to the reference image. This was be done by scrolling through the test images until the right (test) image matched the reference image as closely as possible and the results recorded. All the images were coded and the Radiologists were not aware of the exposure conditions or detector types used.

To confirm the Radiologists' reading consistency, the image positions (left or right monitor) were reversed and a second reading session was done using a reference image from a different detector (CR HD5.0 or DR DX-D30C) and different test images (CR MD 4.0). The average dose reduction for the first set was 58.7%, the average dose reduction for second set was 59.5%. This is a minimal difference.

The primary endpoint was that the test images would demonstrate a minimum of a 50% dose reduction using the CsBR CR (HD5.0) imaging plate and the CsI DR (DX-D30C) detector compared to the BaFBr CR (MD4.0) imaging plate.

The test results showed that a 58% dose reduction was possible with the DX-D30C DR detector and a 60% dose reduction with the HD5.0 CR plates when both were compared to images produced with MD4.0 CR plates which use BaFBr phosphors.

These results are consistent with the technical evaluation of each system and confirm the possibility of at least a 50% dose reduction when comparing CsBr CR (HD5.0) plates or CsI DR (DX-D30C/DX-D35C) detectors to standard CR plates (MD4.0) using BaFBr or other detectors types with similar DQE to standard CR plates.

No animal or clinical studies were performed in the development of the DX-D Imaging Package.

No patient treatment was provided or withheld.

The product, manufacturing and development processes conform to product safety and medical imaging standards including:

PRODUCT STANDARDS

- IEC 60601-1: 2012 Medical Electrical Equipment - Part 1: General Requirements for Safety and Essential Performance.
- IEC 60601-1-2: 2007 Medical Electrical Equipment - Part 1-2: General Requirements For Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
- ACR/NEMA PS3.1-3.20: 2011 Digital Imaging and Communications in Medicine (DICOM)

QUALITY MANAGEMENT STANDARDS

- ISO 14971:2007 Application of Risk Management to Medical Devices
- ISO 13485:2003 Medical Devices - Quality Management Systems - Requirements For Regulatory purposes

G. RISK ASSESSMENT AND MANAGEMENT SUMMARY

During the final risk analysis meeting, the risk management team concluded that the medical risk is no greater than with conventional x-ray film previously released to the field.

There are no residual risks for the released NX software versions NX8800 (NX Ikonos) in the ALARP region after mitigation. Only two risks were identified in the Broadly Acceptable Region. Therefore the device is assumed to be safe, the benefits of the device are assumed to outweigh the residual risk.

The term “Level of Concern” means the level of risk that the software device is determined to be if the software were to fail. The Level of Concern for the device has been determined to be moderate.

H. CONCLUSIONS

The DX-D Imaging Package indications for use is equivalent to both predicates (K122736 and K092238). Both the DX-D Imaging Packag and predicate devices (K122736 and K092238) include the statement that the device is not indicated for mammography, and include pediatric and neonatal patient populations. The predicate device (K092238) includes system options and accessories; which are also available on the DX-D Imaging Package and predicate K122736. Differences in devices do not alter the intended diagnostic effect.

The DX-D Imaging Package and the Agfa HealthCare predicate device (K122736) are solid state imaging devices, Product Code MQB. Agfa HealthCare’s DX-D Imaging Package is substantially equivalent to both predicate devices (K122736 and K092238) in that it uses precisely the same technology to capture and transmit images.

There is no difference between the DX-D Imaging Package and predicate K122736. The DX-D

Imaging Package includes cassettes and image plates which are included in predicate K092238. There are no changes to the intended use/indications of the device. The DX-D Imaging Package uses the same NX Workstation, the same detectors, and same cassettes and image plates as both predicates (K122736 and K092238).

Differences in devices do not alter the intended diagnostic effect. Descriptive characteristics and performance data are adequate to ensure equivalence.

This 510(k) has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.